

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA

v.

RAHIM SHAFI

Defendant.

Crim. No. 20-cr-40021-MRG

**MEMORANDUM AND ORDER ON DEFENDANT’S MOTION FOR BAIL
PENDING APPEAL [ECF NO. 278]**

GUZMAN, J.

On February 9, 2024, following a fourteen-day jury trial, a jury convicted the Defendant, Rahim Shafa, of Counts Two-Four, Aiding and Abetting International Money Laundering (18 U.S.C. §§ 1956(a)(2)(A) and (2)), Counts Six-Eight, Aiding and Abetting Importing Merchandise Contrary to Law (18 U.S.C. §§ 545 and 2), and Count Nine, Receipt and Delivery of Misbranded Drug (21 U.S.C. §§ 331(c) and 333). [ECF No. 195]. On December 16, 2024, the Defendant was subsequently sentenced to a term of imprisonment of thirty-six months followed by a period of supervised release. [ECF No. 276]. Dr. Shafa’s self-surrender date is currently March 14, 2025.

Presently before the Court is Defendant’s motion for bail pending appeal under 18 U.S.C. § 3143(b)(1). [ECF No. 278]. Because the appeals do not raise a substantial question of law or fact that is likely to result in reversal, an order for a new trial, a sentence that does not include a term of imprisonment, or a reduction of sentence, the Defendant’s motion is **DENIED**.

I. LEGAL STANDARDS

When a defendant is sentenced to a term of imprisonment and thereafter appeals their conviction or sentence, the defendant may request that they be released on bail pending the outcome of their appeal. See 18 U.S.C. § 3143(b). However, under 18 U.S.C. § 3143(b), the Court must “order that a person who has been guilty of an offense and sentenced to a term of imprisonment, and who has filed an appeal . . . be detained,” unless the Court determines: (A) “by clear and convincing evidence” that the person is not a flight risk or a danger to the community; and (B) “that the appeal is not for the purpose of delay and raises a substantial question of law or fact likely to result in (i) reversal, (ii) an order for a new trial, (iii) a sentence that does not include a term of imprisonment, or (iv) a reduced sentence less than the total of the time already served plus the expected duration of the appeal process.” 18 U.S.C. § 3143(b)(1).

The First Circuit has explained that 18 U.S.C. § 3143(b) does not create a “presumption in favor of release pending appeal; on the contrary, even when the conviction does not involve a crime of violence or drug offense, detention (following conviction and sentencing) is mandatory unless the judicial officer finds” that the requisite conditions are met. United States v. Colon-Munoz, 292 F.3d 18, 20 (1st Cir. 2002). The inquiry into 18 U.S.C. § 3143(b)(1)(B) encompasses two distinct requirements: “(1) that the appeal raise a substantial question of law or fact and (2) that if the substantial question is determined favorably to defendant on appeal, that decision is likely to result in” acquittal, a new trial, or a reduced sentence. Bayko, 774 F.2d at 522. To establish the existence of a “substantial question,” the defendant must show that there is a “‘close’ question or one that very well could be decided the other way.” United States v. Bayko, 774 F.2d 516, 523 (1st Cir. 1985) (quoting United States v. Giancola, 754 F.2d 898, 901 (11th Cir. 1985)). The mere “possibility of reversal” is not sufficient to satisfy this requirement. Id. Furthermore, questions are

not “substantial” simply because they are “‘novel,’ ‘undecided’ or ‘fairly doubtful.’” *Id.* (rejecting the approach of the Third Circuit in *United States v. Miller*, 753 F.2d 19, 23 (3d Cir. 1985)).

II. DISCUSSION

The Defendant raises several issues that he will present on appeal. The Defendant argues, first, that the Court’s exclusion of Wayne Moran’s prior testimony was erroneous; second, that the Court’s admission of uncharged bad acts was erroneous; third, that the Government introduced testimony that was improper; fourth, that the Court erroneously excluded Defendant’s expert, Benjamin England, from testifying; fifth, that all the actions previously discussed were prejudicial under the doctrine of cumulative error; and sixth, that the Court erred in applying the guidelines during sentencing. The Court considers all of the arguments below.

The Government does not contend that the Defendant is a flight risk. [See ECF No. 284]. The Defendant argues that he has been compliant with his conditions of release for more than four years and that nothing in his background suggests any risk of danger to the public. [ECF No. 278 at 2]. It is arguably shown that the Defendant is not a risk of flight, and that any danger he poses to the community can be mitigated through conditions of release. Furthermore, it is uncontested that the Defendant’s appeals were not filed merely for the purpose of delay. [See ECF No. 278, 284, 287]. Therefore, to succeed, the Defendant must demonstrate that his appeal raises a substantial question of law that is likely to result in reversal, a new trial, a sentence that does not include incarceration, or a reduction of sentence. *See Bayko*, 774 F.2d at 522

A. The Defendant’s Appeal Does Not Raise a Substantial Question of Law or Fact Likely to Result in an Acquittal, New Trial, or Reduced Sentence

1. *Exclusion of Wayne Moran’s Prior Testimony*

The Defendant first argues that the Court erroneously excluded Wayne Moran's prior testimony introduced by the Government in a criminal trial against Lance Gooberman. [ECF No. 278 at 3]. The First Circuit reviews evidentiary rulings "only for an abuse of discretion, 'which favors the prevailing party.'" United States v. Bartelho, 129 F.3d 663, 670 (1st Cir. 1997) (quoting United States v. Omar, 104 F.3d 519, 522 (1st Cir. 1997)). This Court appropriately acted within its discretionary authority when it excluded Wayne Moran's prior testimony based on multiple independently sufficient reasons.

The Defendant filed a motion in limine to admit the trial testimony of Wayne Moran from United States v. Gooberman, Case No. 20-CR-125 (C.D. Cal.). Gooberman was charged with import, export, and Federal Food, Drug, and Cosmetic Act (FDCA) violations relating to naltrexone pellet implants that he exported to a distributor in Hong Kong - Wayne Moran - who then shipped the pellet implants worldwide, including into the United States. Moran was, at the time of the Gooberman trial, a cooperating witness who the Government called to testify about his knowledge of and interactions with Gooberman concerning implant shipments that Gooberman shipped to Moran that Moran then shipped around the world. [ECF No. 284 at 3-4]. The Defendant sought to introduce Moran's Gooberman trial testimony where he stated that he falsified the shipping documents for the pellet implant packages by declaring the contents of the packages as "plastic beads and plastic tubes" and "small glass bottles," rather than the misbranded drugs they actually contained. Moran stated he did so because some unnamed and unidentified Customs official in Anchorage, Alaska first told Moran's practice manager that the packages should be labeled that way, then the practice manager told Moran what they had heard from the Customs official. [Tr. Moran Testimony in Gooberman, 217:17-218:5, ECF No. 164-1]. Dr. Shafa attempted to argue that this testimony showed he lacked the intent to defraud in the transportation of the

pellets because he followed Moran's instructions to mislabel the packages. [ECF No. 147 at 1]. The Court ultimately precluded the Defendant from introducing Moran's testimony.

First, this Court found that the prior trial testimony was not sufficiently relevant to warrant admission under Federal Rule of Evidence 401, 402, and 403. Evidence is not admissible if it is not relevant. Fed. R. Evid. 402. Here, the Court found that the evidence was not relevant because it had to do with a different defendant, a different trial, and in a different venue in the Central District of California. Furthermore, the overwhelming majority of Moran's testimony had nothing to do with the Defendant. In fact, Dr. Shafa was only mentioned twice in the 150 pages of Moran's testimony. [See ECF No. 164 at 3; Tr. Moran Testimony in Gooberman]. Even if the Court considered the testimony relevant, it also found that it would be confusing to the jury. Relevant evidence may be excluded "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. The Court found that Moran's testimony was likely to mislead the jury in the present case because this case did not touch upon Mr. Gooberman or his trial. The testimony had to do with a different defendant that was not central to Dr. Shafa's case. Therefore, the Court found that prior testimony should have been excluded under Rule 401, 402, and 403.

Second, the Court also found that even if the prior testimony was relevant, there were multiple hearsay issues that would preclude admission. First, Moran's statements were hearsay under Federal Rule of Evidence 801 because they were out of court statements of a declarant offered in evidence to prove the truth of the matter asserted. The Defendant attempts to argue that the statements were not being offered for their truth, but rather because the "mere fact that the information was communicated to Moran supported a good-faith belief in the legality of his

actions.” [ECF No. 278 at 8]. This argument is misleading and wrong because it omits the fact that the Defendant still sought to demonstrate that the statements by Moran’s practice manger were true. For a hearsay statement to be admissible, it must meet an exception to hearsay delineated in the Federal Rules of Evidence. “A party who seeks admission of hearsay evidence bears the burden of proving each element of the exception that he asserts.” Bartelho, 129 F.3d at 670 (citations omitted). To admit statements that constitute multi-level hearsay, or “hearsay within hearsay,” as is the case here, the moving party must show that “each part of the combined statements conforms with an exception to the rule.” Fed. R. Evid. 805. The Defendant sought to introduce an out-of-court statement from Moran about what he heard from his practice manager about what they heard from the unidentified customs agent. This statement contains multiple levels of hearsay and admitting such testimony would contradict the purpose of the hearsay rule. United States v. Barone, 114 F.3d 1284, 1292 (1st Cir. 1997) (“The rule against hearsay reflects concerns about the trustworthiness of out-of-court statements, arising from the fact that such statements are not subject to the tests normally applied to in-court testimony to ensure its reliability.”). The Defendant failed to demonstrate that these statements met the exceptions to the rule against hearsay. Therefore, the Court appropriately concluded that the statements contained multiple levels of hearsay that were inadmissible.

The Defendant unsuccessfully attempted to establish the hearsay exception delineated in Federal Rule of Evidence 804(b)(1). To admit prior testimony under Rule 804(b)(1), the moving party must show that “the witness is unavailable to testify in person” and that “the opposing party had ‘an opportunity and similar motive to develop the testimony by direct, cross, or redirect examination.’” Bartelho, 129 F.3d at 670 (quoting Fed. R. Evid. 804(b)(1)). The inquiry into “similar motive” is 1) “whether the questioner is on the same side of the same issue at both

proceedings,” and 2) “whether the questioner had a substantially similar interest in asserting that side of the issue.” *Id.* at 671 (quoting United States v. DiNapoli, 8 F.3d 909, 912 (2d Cir. 1993)). This inquiry “requires scrutiny of the factual and procedural context of each proceeding to determine both the issue in dispute and the intensity of interest in developing the particular issue by the party against whom the disputed testimony is offered.” *Id.*

Here, the Court concluded that the Defendant failed to demonstrate that the Government had a similar motive in developing Moran’s testimony in the Gooberman trial. When evaluating the Government’s motive, “it is the government’s interest in the particular proceeding, as prosecutor, not its broader interest in achieving justice, as a sovereign, that must be examined.” Bartelho, 129 F.3d at 67 (citations omitted). The Government’s motive in the Defendant’s trial was different because Moran would serve as an adverse witness. Unlike in Gooberman, the Government here would have challenged Moran’s credibility as well as the credibility of the specific statements sought to be introduced. Second, in Gooberman, the Government did not thoroughly question Moran about his relationship with the Defendant. In fact, most of the drugs that the Defendant and Moran conspired to illegally import had nothing to do with Gooberman. Finally, the Government, focusing on Gooberman, did not elicit further testimony about Moran’s interaction with the Defendant about the customs agent testimony nor did it challenge the veracity or limitations of such testimony. Because of the limited nature of the previous testimony and the different motives of the Government, the Court rightfully rejected the Defendant’s arguments.

This Court had substantial evidentiary reasons to exclude Moran’s testimony from the proceeding and this exclusion does not raise a substantial issue of law or fact. The Defendant fails to show how this determination is not within the Court’s discretionary authority. Therefore, the Court finds that the Defendant failed to demonstrate a substantial question of law, and instead only

showed a question comfortably within the court's discretionary authority. See United States v. Diaz-Colon, 729 F.Supp.3d 232, 239-39 (D.P.R. 2024) (holding that no substantial question of law existed when the court excluded inadmissible evidence). The Defendant has therefore failed to demonstrate that his appeal will raise a substantial question of law based on any exclusion of prior testimony.

2. *Admission of Uncharged Bad Acts*

The Defendant also argues that the Court erroneously allowed Government witnesses to prejudicially testify about the Defendant's treatment of patients. Specifically, the Defendant challenges two types of testimony as constituting irrelevant "uncharged bad acts": (1) the testimony of three former students discussing the Defendant's supervision of them and their observations of the Defendant's interaction with patients; and (2) testimony of three former patients discussing their wait times, the nature of implant procedures, and medical complications they suffered. [ECF No. 278 at 10-11]. The First Circuit reviews admission of evidence over objection for abuse of discretion. United States v. Vazquez-Rivera, 665 F.3d 351, 357 (1st Cir. 2011). Unpreserved objections are reviewed for plain error. Id. To establish plain error, the defendant must show "(1) an error occurred (2) which was clear or obvious and which not only (3) affected [] substantial rights, but also (4) seriously impaired the fairness, integrity, or public reputation of judicial proceedings." Id. (citations omitted) (alteration in original). "The plain error hurdle is high." United States v. Hunnewell, 891 F.2d 955, 956 (1st Cir. 1989). While Defendant preserved his objections on some aspects of the contested testimony, other aspects were not clearly

objected to.¹ Still, the Court was justified in allowing the contested testimony under either abuse of discretion or plain error review.

Defendant's appeal implicates three Federal Rules of Evidence: Rules 402, 404(b), and 403. Under Rule 402, relevant evidence is generally admissible, while "[i]rrelevant evidence is not admissible." Fed. R. Evid. 402. Rule 404(b) stipulates that "[e]vidence of any other crime, wrong, or act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." Fed. R. Evid. 404(b)(1). The First Circuit has held that "[w]here a defendant challenges a district court's admission of [other] bad acts evidence [under Rule 404(b)], the first question for a reviewing court is whether the objected-to evidence has 'special relevance' to the case, by which we mean that the objected-to evidence is relevant for any purpose apart from showing propensity to commit a crime." United States v. Pena, 24 F.4th 46, 65 (1st Cir. 2022) (quoting United States v. Habibi, 783 F.3d 1, 2 (1st Cir. 2015) (internal quotation marks and citation omitted) (alterations in original)). Such other purposes can include "proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." United States v. Romero-Lopez, 695 F.3d 17, 22 (1st Cir. 2012) (quoting

¹ [Trial Tr. Day 2 63-78, ECF No. 214] (former student testifying about experience working under Defendant without objection to general testimony); [Trial Tr. Day 5 66-78, ECF No. 216] (former student testifying about experience working under Defendant, his observations of Defendant's interaction with patients, and the unsterile nature of the implant procedures without objection to general testimony but testifying over objection about why the procedure being used was "unusual"); [Trial Tr. Day 9 112-129, ECF No. 220] (former student testifying about observations of implant procedures without objection but testifying over objection about concerns with the patients' quality of care and the lack of discussion with patients regarding risks and benefits). [Trial Tr. Day 5 13-29, ECF No. 216] (former patient testifying about experience with drug addiction and nature of the implant procedures without objection to general testimony); [Trial Tr. Day 7 48-65, ECF No. 218] (former patient testifying about experience receiving implant and medical complications suffered without objection to general testimony but testifying over objection about how her treatment with other doctors was a collaborative process as opposed to feeling like the Defendant was trying to sell her something).

Fed. R. Evid. 404(b)(2)); see also United States v. Landry, 631 F.3d 597, 602 (1st Cir. 2011) (explaining that Rule 404(b)'s list of permissible purposes is illustrative and not exhaustive). Even if the evidence has “special relevance,” the Court must then “evaluate the evidence’s admissibility under Rule 403, specifically, whether its ‘probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.’” Pena, 24 F.4th at 65-66 (citing Fed. R. Evid. 403).

The evidence in question was relevant; was admitted for the purposes of proving intent, plan, lack of accident, and knowledge; and was not unfairly prejudicial. The Defendant summarizes the contested evidence as follows:

The former students testified that Dr. Shafa provided insufficient supervision, performed pellet implant procedures in a dark, dirty room with insufficient sterilization (in one instance using an expired anesthetic), provided insufficient advice to patients regarding the risks involved in the procedures, and even fell asleep during patient appointments. See Jan. 24, 2024 Tr. 63-78; Jan. 27, 2024 Tr. 66-78; Feb. 2, 2024 Tr. 112-129. The patients testified about their struggles with addiction at the time they saw Dr. Shafa, the wait times to see the doctor (with one witness testifying she waited 12 hours), the intrusive nature of the implant procedures, medical complications they suffered (and in some cases continued to suffer) as a result, and their relapsing after being treated by Dr. Shafa. See Jan. 27, 2024 Tr. 13-29; Jan. 31, 2024 Tr. 48-65; Feb. 2, 2024 Tr. 141-42.

[ECF No. 278 at 11]. “To be relevant, evidence need only tend to prove the government’s case, and evidence that adds context and dimension to the government’s proof of the charges can have that tendency. Relevant evidence is not confined to that which directly establishes an element of the crime.” United States v. Mangual-Santiago, 562 F.3d 411, 428 (1st Cir. 2009) (citation omitted). The evidence above added context to the Government’s case and specifically rebutted the defense’s argument that Dr. Shafa was a “good doctor.” While his professional standards, or lack thereof, were not on trial, his deviation from standard medical protocols and the surreptitious nature of how he conducted his implant practice indicated his intentional and knowing violation

of the law – a mens rea that the Government was required to prove for conviction. In particular, the testimony demonstrated that the Defendant was storing the pellets in abnormal locations such as his personal refrigerator, and that the Defendant was not performing the implant surgeries in a normal operating room during business hours but would wait until late at night, perform the surgeries in the dark, without any standard protection gear, lacking proper sanitation, and would implant the patients in a small office space rather than an exam room. Although the Defendant now attempts to argue that these facts would not prove that he was “smuggling, money laundering, and misbranding,” the evidence is directly relevant to prove that he knew he was acting illegally. See Huddleston v. United States, 485 U.S. 681, 685 (1988) (“Extrinsic acts evidence may be critical to the establishment of the truth as to a disputed issue, especially when that issue involves the actor’s state of mind and the only means of ascertaining that mental state is by drawing inferences from conduct.”).

Despite the defense’s attempts to paint Dr. Shafa as a law-abiding doctor with innocent intent, the contested evidence showed that his illegal naltrexone implant procedures were part of a plan, were not an accident, and were repeated over and over again to Dr. Shafa’s financial benefit. The contested testimony therefore had “special relevance” and was admissible for those exact purposes, which are specifically contemplated by the Federal Rules of Evidence. See Romero-Lopez, 695 F.3d at 22 (Permissible purposes for admitting 404(b) evidence include “motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident.”) (quoting Fed. R. Evid. 404(b)(2)).

Further, Dr. Shafa’s failure to provide full information to patients regarding the risks involved in the procedures, the unsanitary and intrusive nature of the procedure, and the patients’ complications and relapses after treatment are all relevant to the misbranding charge, the

Defendant's purported affirmative defense of the FDA's Personal Importation Policy, and sentencing. The misbranding element of Count 9 relied on whether the drug in question had adequate instructions for use and whether its labeling was false and misleading. [See Trial Tr. Day 13 121:15-122:19 (Jury Instructions, Count 9)]. Moreover, Count 9 required the Government to prove that Dr. Shafa actually delivered the drugs to patients. [Id. at 120:16-19]. Thus, Dr. Shafa's shoddy interactions with patients and the incomplete nature of the disclosures he gave them regarding medical treatment are relevant to those elements. As discussed *infra* in the analysis regarding defense expert Benjamin England, the Defendant sought jury instructions on the FDA's Personal Importation Policy (PIP) as an affirmative defense. Under this policy, the FDA permits some personal importation of unapproved drugs on a case-by-case basis, provided the drugs are for personal use, and such use does not appear to present an unreasonable risk to the individual. FDA, *Regulatory Procedures Manual (RPM) Chapter 9-2 (Version 05)* (emphasis added). The testimony of the patients and former students was relevant to the last condition of the policy: that the use does not appear to present an unreasonable risk to the individual. The contested testimony squarely established that Dr. Shafa's implantation procedures *did* present an unreasonable risk of bodily harm to his patients – risks of infection, failure of the implant leading to relapses, and potential complications from negative drug interactions, given that Dr. Shafa failed to disclose that the naltrexone implants also contained triamcinolone – a powerful steroidal drug and immunosuppressant. Dr. Shafa's conduct putting his patients at risk of bodily harm was likewise relevant at sentencing as he received a two-point enhancement because his offense involved the "conscious or reckless risk of death or serious bodily injury to another." USSG § 2B1.1(b)(16)(A); [PSR ¶¶ 50].

Admission of the testimony did not result in unfair prejudice, rather any danger of prejudice faced by the Defendant was substantially outweighed by the testimony's probative value, as summarized above. See Fed. R. Evid. 403. Additionally, the defense had ample opportunity to challenge the testimony in cross examination. While the testimony reflected negatively on Dr. Shafa, the Defendant may not dictate how the prosecution depicts him through admissible evidence confined by the Federal Rules. See United States v. Villa-Guillen, 102 F.4th 508, 518 (1st Cir. 2024) ("Because 'by design, all evidence is meant to be prejudicial,' a district court's rulings under Rule 403 must avoid 'only unfair prejudice.'" (quoting United States v. Morales-Aldahondo, 524 F.3d 115, 119-20 (1st Cir. 2008) (internal quotation marks and citation omitted))).

As the Court did not err in admitting the testimony of students and patients under either the plain error or abuse of discretion standard, the Defendant has failed to demonstrate that his appeal will raise a substantial question of law based on the admission of that testimony.

3. *Testimony of Government's Expert*

The Defendant next argues that the Court erroneously allowed the Government's expert witness, Dr. Arthur Simone, to testify about what "misbranding" is. A court's admission of expert testimony is reviewed for abuse of discretion. Milward v. Acuity Specialty Prods. Grp., Inc., 639 F.3d 11, 13 (1st Cir. 2011). Expert testimony is allowed if "scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue" Nieves-Villanueva v. Soto-Rivera, 133 F.3d 92, 100 (1st Cir. 1997) (quoting Fed. R. Evid. 702). However, "[e]xpert testimony that consists of legal conclusions cannot properly assist the trier of fact in either respect" Id. (quoting Burkhart v. Washington Metro. Area Transit Auth., 112 F.3d 1207, 1212 (D.C. Cir. 1997)). Plainly put, "an expert may offer his opinion as to facts that, if found, would support a conclusion that the legal standard at issue was satisfied, but

he may not testify as to whether the legal standard has been satisfied.” Burkhart, 122 F.3d at 1212-13.

Here, Dr. Simone was permissibly allowed to testify about the concepts of misbranding and the Food, Drug & Cosmetic Act because these were topics that would not be known by an average juror and required expert testimony. Dr. Simone testified about examples that could be classified as misbranding but at no point did he testify about a legal conclusion nor did he testify that the Defendant was guilty of misbranding. Therefore, the Court found that the testimony provided by Dr. Simone did not go beyond the scope allowed by Rule 702.

However, even if the testimony was found to exceed the scope of 702, the Defendant has failed to demonstrate that such error was not harmless. Here, the Court provided explicit instructions to the jury that they “have to use the law as [the Court] give[s] it to [them].” [Trial Tr. Day 13 92:17-19, ECF No. 224]. The Court then provided explicit instructions on the legal definition of misbranding and stated that they must focus on the “three ways” that were at issue. [Id. at 121:15-122:19]. The First Circuit has found that when a court clearly instructs the jury to the central issues, the impact of legal conclusions opined by an expert are negated. Nieves-Villanueva, 133 F.3d at 102-03. Therefore, even if the expert testimony is found to have introduced legal conclusions, which this Court does not believe it did, any testimony is harmless because the Court provided clear instructions about what law the jurors should apply and reinforced that the central issue was solely for the jurors to decide.

The Defendant has therefore failed to demonstrate that his appeal will raise a substantial question of law based on any admittance of expert testimony reasonably within the trial court’s discretion.

4. *Exclusion of the Defendant's Expert, Benjamin England*

The Defendant also argues that the Court erroneously excluded the testimony of his proposed expert, Benjamin England. As discussed earlier, a court's admission of expert testimony is reviewed for abuse of discretion. Milward, 639 F.3d at 13. Here, the Defendant sought to introduce England as an expert witness to testify about U.S. Food and Drug Administration ("FDA") regulations related to "compounding" and the "Personal Import Policy." [See generally Def.'s Further Mot. to Permit Expert Test., ECF No. 186].

As a preliminary matter, this Court found that England lacked the qualifications that would make his testimony relevant or helpful to the jury. England worked for the FDA more than twenty years before the Defendant's trial and more than five years before any of the conduct alleged in the Indictment began. Furthermore, England never worked for any positions in the FDA that regulated compounding.

a. *England's Testimony on Compounding*

First, the Court found that issue of compounding, as the Defendant raised it, was an affirmative defense. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), 21 U.S.C. § 353a(a), "a licensed pharmacist is exempt from federal liability where he compounds a drug product 'for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation,'" provided that certain conditions are met. United States v. Bader, 678 F.3d 858, 887 (10th Cir. 2012), cert. denied, 568 U.S. 888 (2012) (quoting 21 U.S.C. § 353a(a)). The FDAMA therefore presents an affirmative defense" Bader, 678 F.3d at 887. To be entitled to present an affirmative defense at trial, the defendant must "carry [an] entry-level burden of adducing competent proof" of the defense. United States v. Maxwell, 254 F.3d 21, 26 (1st Cir. 2001). Further, "[t]he constitutional right of the defendant to a fair trial is not

diminished if the defendant is precluded from raising defenses for which she can present no supporting evidence at all.” United States v. Brodhead, 714 F. Supp. 593, 596 (D. Mass. 1989) (citation omitted). The “entry-level burden” requires the defendant to “present ‘more than a scintilla of evidence’ that demonstrates that he can satisfy the legal requirements for asserting the proposed defense.” United States v. Garrito Fort, No. 22-cr-090-SE, 2023 U.S. Dist. LEXIS 169918, at *6 (D.N.H. Sept. 25, 2023) (citing United States v. Winnett, No. 02-10272-RBC, 2003 U.S. Dist. LEXIS 10796, at *4 (D. Mass. June 23, 2003) (citation omitted)).

The Defendant failed to meet his burden to show that he was entitled to present evidence of the compounding affirmative defense. There was not any evidence introduced by the government that any of the drugs at issue were or could have been compounded. There was also not even a “mere scintilla” of evidence to support that compounding was plausible in this case. There was no evidence that the drugs in question were even compounded besides testimony from Moran in Gooberman that the Court precluded. Second, there was no evidence that Moran was a licensed pharmacist; no evidence that the drugs were imported for an identified individual patient; and no evidence that the drugs were ordered pursuant to a valid prescription. See 21 U.S.C. § 353a(a). In fact, the evidence at trial showed that Dr. Shafa imported the pellet implants in bulk for multiple patients and that he never wrote prescriptions for the implants for his patients. Therefore, the issue of compounding was entirely irrelevant in this case and England’s testimony would have been misleading for the jury. As a result, the Court properly excluded England’s testimony on compounding.

b. England’s Testimony on Personal Importation Policy

As with compounding, the FDA’s Personal Importation Policy (“PIP”) has been characterized as a “defense” to FDA violation charges. See United States v. Briner, No. 05-64,

2005 U.S. Dist. LEXIS 31573, at *25 (E.D. Pa. Dec. 6, 2005). Therefore, to use it at trial, the Defendant must “carry [an] entry-level burden of adducing competent proof” of the defense. Maxwell, 254 F.3d at 26. The FDA permits some personal importation of unapproved drugs on a case-by-case basis, provided the drugs are for personal use, and such use does not appear to present an unreasonable risk to the individual. FDA, *Regulatory Procedures Manual (RPM) Chapter 9-2 (Version 05)*. The FDA has generally allowed individuals to bring into the United States a 90-day supply of unapproved drugs for personal use where effective treatment is not available in the United States, it is for the treatment of a serious medical condition, and there is no commercialization of the drug to U.S. residents. Id.; AMANDA K. SARATA, CONG. RSCH. SERV., IF11056, PRESCRIPTION DRUG IMPORTATION (2024). PIP was not relevant in this case because (1) the drugs the Defendant imported were indisputably not for personal use; (2) the quantities imported exceeded a 90-day supply; (3) there are other effective treatments for opioid use disorder in the United States; and (4) Dr. Shafa charged his patients money for the implants, meaning he commercialized the drug to U.S. residents. Therefore, the Court concluded that allowing England’s testimony on PIP was irrelevant under Rule 401 and likely to confuse or mislead the jury under Rule 403.

This Court’s finding aligns with other courts that have excluded the testimony of England for the very same reasons. In United States v. Gooberman,² England was precluded from testifying about the FDA’s personal importation policy because it was irrelevant testimony and confusing to the jury. In United States v. Javat,³ England was precluded from testifying about uncharged FDA laws and regulations governing imports because it was irrelevant, confusing, and misleading. The

² United States v. Gooberman, 2:20-CR-00125, (C.D. Cal.).

³ United States v. Javat, 18-CR-20668, (S.D. Fla.).

Defendant has failed to demonstrate that this Court exceeded its discretionary authority in excluding expert testimony. Therefore, the Defendant has not provided a substantial question of law or fact likely to result in acquittal, new trial, or reduced sentence.

5. *Analysis of Cumulative Error*

Here, the Defendant makes four discrete claims of error in the Court’s conduct of the trial, which, he contends that if taken together, are likely to result in reversal.

The rubric of cumulative error demands that trial errors be weighed “against the background of the case as a whole, paying particular weight to factors such as the nature and number of the errors committed; their interrelationship, if any, and combined effect; how the district court dealt with the errors as they arose (including the efficacy—or lack of efficacy—of any remedial efforts); and the strength of the government’s case.”

United States v. Sanabria, 645 F.3d 505, 516-17 (1st Cir. 2011) (quoting United States v. Sepulveda, 15 F.3d 1161, 1196 (1st Cir. 1993)). As discussed, this Court does not find that any of the alleged errors have occurred. Furthermore, the Court has also found that even if any error did occur, they were harmless and unlikely to result in reversal. Therefore, the cumulative error doctrine is not applicable to the Defendant. See United States v. DeSimone, 699 F.3d 113, 128 (1st Cir. 2012) (“The cumulative error doctrine is of no use to [the defendant] because the only identified error was harmless.”).

6. *Application of Sentencing Guidelines*

The Defendant’s final argument is that the Court erred in applying the U.S. Sentencing Guidelines, namely, that it improperly applied the fraud cross reference found in U.S.S.G. § 2N2.1. The Defendant argues that the issue surrounding the application of guidelines in this case is a substantial question because it “represents a novel question, which may well be decided the other way by the First Circuit.” [ECF No. 278 at 23]. However, as discussed earlier, questions are not “substantial” simply because they are “‘novel,’ ‘undecided’ or ‘fairly doubtful.’” Bayko, 774 F.2d

at 523. Also, the fact that there is a possibility of reversal is not sufficient to make this a substantial question. Id. (“The finding made by the district court was that there was ‘a possibility of reversal.’ This cannot mean ‘a “close” question or one that very well could be decided the other way.’”). Furthermore, the Court did not err in applying the guidelines during sentencing.

The Court properly applied the fraud cross reference in sentencing Dr. Shafa. For reasons elaborated on in the PSR, the offense level for Count 9 governed the guidelines calculation. [See PSR ¶¶ 41-46]. The guideline for a violation of 21 U.S.C. § 331(c) (Count 9) is USSG § 2N2.1. The “fraud cross reference” refers to the cross reference at § 2N2.1(c)(1), which mandates that § 2B1.1 is used to determine the offense level “[i]f the offense involved fraud.” USSG § 2N2.1(c)(1). Section 2B1.1(b)(1) contains a specific offense characteristic loss table that increases the offense level based on the amount of loss from the offense. The Government’s Amended Victim Table [ECF No. 259-1] calculated the total loss as \$448,894.00, corresponding to the amount Dr. Shafa received from patients for the misbranded pellet implants during the indicted period of January 2008 to January 2018. That amount in reference to the loss table in § 2B1.1(b)(1)(G) resulted in a 12-point enhancement.

Under the November 2024 amendments to the U.S. Sentencing Guidelines, “[r]elevant conduct does not include conduct for which the defendant was criminally charged and acquitted in federal court, unless such conduct also establishes, in whole or in part, the instant offense of conviction.” USSG § 1B1.3(c). The Defendant objected to applying the fraud cross reference because, although the jury convicted him of Count Nine (receipt and delivery of a misbranded drug), the jury acquitted him acting with the intent to defraud. [See Jury Verdict at 10, ECF No. 197]. The Defendant seems to view the “offense of conviction” in question as solely Count 9; however, he fails to account for the fact that all the convicted counts together make up the instant

offense of conviction because the guidelines were calculated by treating the counts as a single criminal objective or plan, and, therefore, a single group. [See PSR ¶ 43]. The PSR concluded that all the counts should be grouped together for two independent reasons. [PSR ¶¶ 41-46]. One of those reasons stemmed from the directive of USSG § 3D1.2(b), which states that counts are to be grouped together when the “counts involve the same victim and two or more acts or transactions connected by a common criminal objective or constituting part of a common scheme or plan.” USSG § 3D1.2(b); [PSR ¶ 43].

Dr. Shafa was convicted of international money laundering (Counts 2-4), importing merchandise contrary to law (Counts 6-8), and receipt and delivery of misbranded drugs (Count 9). [Jury Verdict]. His offenses of conviction were part of a common scheme or plan comprising of three parts: paying Moran for the naltrexone implants, importing the drugs, then selling them/delivering them to patients. Additionally, all the counts involved the same ultimate victims: Dr. Shafa’s patients. This reading of “victim” is supported by the PSR and the Government’s “Victim Table,” which both included only Dr. Shafa’s patients as victims. Therefore, all the counts are grouped together and form the “instant offense of conviction,” and when the Court considered the presence of fraud as relevant conduct, it looked at all the counts together, not just Count 9 in isolation.

The Court correctly concluded that fraud was relevant conduct that “establishe[d], in whole or in part, the instant offense of conviction.” See USSG § 1B1.3(c). There were multiple types of fraudulent conduct at play in Dr. Shafa’s offenses, including fraud against U.S. Customs in illegally importing the drugs and mislabeling shipping documents; fraud against the FDA in flouting regulations and receiving and delivering misbranded drugs; and fraud against his patients regarding the length of implant duration, the presence of an undisclosed drug, misstatements of

side effects in disclosures, and improper packaging labels in a foreign language. Further, the jury instructions for Counts 6-8 included a requirement of knowingly concealing unlawfully imported merchandise. [See Trial Tr. Day 13 117:11-118:8].⁴ The Court finds the absence of the word “fraud” in the elements to be of no consequence; intentional deceit and concealment carry the same meaning as fraud in this context.

Accordingly, the Court did not run afoul of the 2024 Amendment that limited the use of relevant conduct for acquitted offenses. Indeed, it did not rely solely on Count 9 in applying the fraud cross reference but considered all counts together as the instant offense of conviction. That the acquitted conduct amendment is new or novel does not mean it creates a “substantial question” on appeal. See Bayko, 774 F.2d at 523. As the Court did not err, the likelihood of reversal on appeal is low – and mere possibility of reversal is likewise insufficient to make raise a substantial question warranting bail pending appeal. See id.

B. Any Favorable Decision is Not Likely to Result in an Acquittal, New Trial, or Reduced Sentence

For a sentence to be stayed pending appeal, a defendant must not only demonstrate that the appeal raises a substantial question of law, but he must also show that “if that substantial question is determined favorably to defendant on appeal, that decision is likely to result in” acquittal, a new trial, or a reduced sentence. Bayko, 774 F.2d at 522. This second requirement “has generally been read to mean that if error is found, it must not be harmless or unprejudicial error.” Id. This requires

⁴ “Defendant Rahim Shafa . . . is charged in Counts Six, Seven, and Eight with those very elements of receiving, concealing, buying, selling, or facilitating the transportation, or concealment, or sale of unlawfully imported merchandise . . . you must be convinced beyond a reasonable doubt of . . . [s]econd, Defendant Rahim Shafa received, bought, sold and/or in any manner facilitated the sale of the merchandise described above knowing that it had been imported or brought into the United States contrary to law.” [Trial Tr. Day 13 117:11-118:8].

“that ‘it is more probable than not that’ a favorable decision will result in a reversal of the conviction or a new trial.” Id.

Though the Court has found that it is unlikely that there would be a favorable decision on appeal, it also notes that, even if there were a favorable decision, many of the issues discussed above would result in, at most, harmless error. The evidence presented during the fourteen-day trial was substantial. Even if the appellate court were to find that some testimony was admitted in error, it is unlikely that those decisions would result in an acquittal, new trial, or reduced sentence given the weight of the evidence involved in this case and the clear jury instructions given. See, e.g., United States v. Gurry, No. 16-10343, 2020 U.S. Dist. LEXIS 38273, at *31 (D. Mass. Mar. 5, 2020) (“Even if the appellate court were to find that some witness testimony was admitted in error or were to agree with the Court that the Government’s statements in its closing rebuttal were improper, it is unlikely that those decisions would result in an acquittal, new trial, or a reduced sentence given the weight of the evidence involved in this case.”).

III. CONCLUSION

The appeal does not raise a substantial question of law or fact that is likely to result in reversal, an order for a new trial, a sentence that does not include a term of imprisonment, or a reduction of sentence. Accordingly, the motion for bail pending the Defendant’s appeal is **DENIED.**

SO ORDERED.

Dated: March 3, 2025

/s/ Margaret R. Guzman
Margaret R. Guzman
United States District Judge